Office for Human Research Protections (OHRP)

FEDERALWIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS

A. TERMS OF THE FEDERALWIDE ASSURANCE FOR INSTITUTIONS WITHIN THE UNITED STATES

1. All of the institution's human subject activities, and all human subject activities of the Institutional Review Boards (IRBs) designated under the Assurance, regardless of funding source, will be guided by the ethical principles in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. The following terms apply whenever (a) IRBs operated by the institution provide review and oversight of Federally-supported human subject research, regardless of where the research takes place or by whom it is conducted; or (b) the institution becomes engaged in Federally-supported human subject research. The institution becomes so engaged whenever (a) the institution's employees or agents intervene or interact with living individuals for purposes of Federally-supported research; (b) the institution's employees or agents obtain, release, or access individually identifiable private information for purposes of Federally-supported research; or (c) the institution receives a direct Federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

3. Federally-supported human subject research for which the IRB provides review and oversight will comply with the Federal Policy* (Common Rule) for the Protection of Human Subjects. All human subject research supported by the Department of Health and Human Services (HHS) will comply with all Subparts of HHS regulations at Title 45 Code of Federal Regulations Part 46 (45 CFR 46). All Federally-supported human subject research will also comply with any additional human subject regulations and policies of the supporting Department or Agency. All Federally-supported human subject research will comply with any human subject regulations and policies of any relevant regulatory Department or Agency.

* 7 CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 1230	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission
22 CFR 225	Agency for International Development
24 CFR 60	Department of Housing and Urban Development
28 CFR 46	Department of Justice
32 CFR 219	Department of Defense
34 CFR 97	Department of Education

38 CFR 16	Department of Veterans Affairs
40 CFR 26	Environmental Protection Agency
45 CFR 46	Department of Health and Human Services
45 CFR 690	National Science Foundation
49 CFR 11	Department of Transportation
By Executive Order	Central Intelligence Agency
By Statute	Social Security Administration

4. Except for research exempted or waived under Sections 101(b) or 101(i) of the Federal Policy, all human subject research will be reviewed, prospectively approved, and subject to continuing oversight by the designated IRBs. The IRBs will have authority to approve, require modifications in, or disapprove the covered human subject research.

5. Except where specifically waived or altered by the IRB under Sections 101(i), 116(c) and (d), or 117(c) of the Federal Policy, all human subject research will require written informed consent, in nonexculpatory language understandable to the subject (or the subject's legally authorized representative), including the following basic elements per Section 116(a) and (b) of the Federal Policy: (a) Identification as research; purposes, duration, and procedures; procedures which are experimental; (b) Reasonably foreseeable risks or discomforts; (c) Reasonably expected benefits to the subject or others; (d) Alternative procedures or treatments, if any, that might be advantageous to the subject; (e) Extent of confidentiality to be maintained; (f) Whether compensation or medical treatment are available if injury occurs (if more than minimal risk); (g) Whom to contact for answers to questions about the research, subjects' rights, and research related injury; (h) Participation is voluntary; refusal to participate, or discontinuation of participation, will involve no penalty or loss of benefits to which subject is entitled; and (i) When appropriate, additional elements per Section 116(b) of the Federal Policy.

6. The institution and the designated IRBs have established (or will establish within 90 days), and will provide to OHRP upon request, written procedures for (a) verifying whether proposed activities qualify for exemption from, or waiver of, IRB review; (b) conducting IRB initial and continuing review, approving research, and reporting IRB findings to the investigator and the institution; (c) determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred; (d) ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject; and (e) ensuring prompt reporting to the IRB, institutional officials, the relevant Department or Agency Head, any applicable regulatory body, and OHRP of any (i) unanticipated problems involving risks to subjects or others in any covered research; (ii) serious or continuing noncompliance with Federal, institutional, or IRB requirements; and (iii) suspension or termination of IRB approval for Federally-supported research.

7. The Institutional Signatory Official, the Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person), and the IRB Chairpersons) will personally complete the relevant OHRP basic educational modules, or comparable training approved by OHRP, prior to submitting the Assurance. Members and staff of the IRBs will complete relevant training before reviewing human subject research. Research

investigators must complete appropriate institutional training before conducting human subject research.

8. The institution and the designated IRBs have established (or will establish within 90 days), and will provide to OHRP upon request, education and oversight mechanisms (appropriate to the nature and volume of its research) to verify that research investigators, IRB members and staff, and other relevant personnel maintain continuing knowledge of, and comply with, relevant Federal regulations, OHRP guidance, other applicable guidance, State and local law, and institutional policies for the protection of human subjects. The institution and the designated IRBs will require documentation of such training from research investigators as a condition for conducting HHS-supported human subject research.

9. The institution is responsible for verifying that IRBs designated under the Assurance agree to comply with items (1) through (8) above and that the IRBs possess appropriate knowledge of the local context in which research for which they are responsible will be conducted.

10. This institution is responsible for ensuring that all institutions and investigators collaborating in its Federally-supported human subject research operate under an appropriate Assurance of Protection for Human Subjects. All institutions engaged in such research, including subcontractors and subgrantees, must hold their own Assurance.

11. The institution will provide IRBs that it operates with resources, professional staff, and support staff sufficient to carry out their responsibilities efficiently and effectively.

12. The activities of individual research investigators who are not employees or agents of the institution may be covered under the Assurance only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and IRB oversight. (OHRP's sample Unaffiliated Investigator Agreement may be used or adapted for this purpose, or the institution may develop its own such commitment agreement.) Institutions must maintain such commitment agreements on file and provide copies to OHRP upon request.

13. Information provided under this Assurance should be updated every 36 months, even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the institution's Federalwide Assurance of Protection for Human Subjects.

[X New Filing [] Update for Assurance Identifier:

Department of Health and Human Services
Federalwide Assurance of Protection for Human Subjects

(1) Institution Name: **Washington State Department of Labor & Industries**

City: **Olympia** State: (if USA) **WA** Country: (if outside USA):

IIHS Institution Profile File (IPF) code, if known: **NA**

Federal Entity Identity Identification Number (EIN), if known: **91-600-1069**

assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document. (*indicate below*)

[X] **Domestic Institutions:** [X] ***The Belmont Report***

(choose one)

[] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

[] **International Institutions:** [] ***Declaration of Helsinki*** [] ***The Belmont Report***

(choose one)

[] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

(2) This institution assures that all of its activities related to Federally-supported human subject research will comply with the following procedural standards. (*indicate below*)

[X] **Domestic Institutions:** *(choose one)* [X] **45 CFR 46 as Stipulated in the Terms of Assurance for Protection of Human Subjects Within the United States,** provided on the OHRP website.

[] ***Other:*** *(Please submit copy to OHRP with this Assurance)*

(please check one of the following)

[X] This institution elects to assure compliance with the Terms of Assurance for all of its human subject research, regardless of funding source.

[] This institution assures compliance with the Terms of Assurance only for Federally-supported research.

[] **International Institutions:** **Terms of Assurance for Protection of Human Subjects Within the United States,** provided on the OHRP website and

in the standards below.

(please check one of the following)

[] 45 CFR 46, 21 CFR 50, and 21 CFR 56

[] ICH-GCP-E6 Sections 1-4

[] Canadian Tri-Council Policy

[] Indian Council of Medical Research

[] CIOMS International Ethical Guidelines

[] Other (Please submit copy to OHRP with this Assurance)

(3) Institutional Components

List below all components of the institution that may operate under a different name [e.g., All Saints Medical Center is comprised of All Saints Hospital, St. Mary's Children's Hospital, St. Mathias Psychiatric Hospital, and St. Paul's Rehabilitation Center]. Also list any alternate names under which the institution may operate. The institution should have available, for review upon OHRP request, a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the IRB, IRB support staff, and investigators in the various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the named institution and all components listed here. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

[] Please check here if there are no such components or alternate names.

Name of Component	City	State (or Country if Outside US)
Washington State Department of Labor & Industries **Insurance Services** **WISHA Services** **Specialty Compliance Services** **Administrative Services** **Safety and Health Assessment and Research for Prevention (SHARP)** **Office of the Medical Director** **Health Services Analysis** **Planning and Research Services**	**Tumwater**	**Washington**

(4) Operations, Procedures, and Oversight Mechanisms (a, b, c, e = optional)

(a) Institutional procedures for protecting human subjects were last updated on: *(07/01/98)*

(b) These procedures include formal mechanisms for monitoring compliance with human subject protection requirements. [x] *Yes* [] *No*

(c) The institution has established continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements. [X] *Yes* [] *No*

(d) For Domestic Institutions, the Signatory Official, Human Protections Administrator, and IRB Chairpersons of all designated IRBs have completed the relevant OHRP modules(s), and other staff are appropriately trained. For International Institutions, relevant personnel are required to complete appropriate comparable training. [X *Yes* [] *No*

(e) Number of full time positions devoted solely to human subject education activities: 0

(f) If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

(5) Designation of Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs)

This institution designates the following IRB(s) for review of research on a regular basis* under this Assurance *(if the IRB is not previously registered with HHS or has not provided a membership roster to HHS, please attach the necessary materials available elsewhere on this website).*

* Institutions may, on an occasional or ad hoc basis, choose to rely on an IRB operating under another Institution's Assurance. Such occasional reliance must be documented in writing and provided to OHRP upon request, but need not be listed below. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions may develop their own agreement.

HHS IRB Registration Identifier	**Name of IRB As Registered with HHS**	**Name and Signature of IRB Chairperson or IRB Organization Head Authorizing Designation of the IRB Under This Assurance**
IRB000000093-01 IRB00000094-02	DSHS/DOH Human Research Review Board A. DSHS/DOH Human Research Review Board B.	Sharon Estee, PhD, Chair Sharon Estee DSHS/DOH Human Research Review Board A. Lillian Bensley, PhD Chair Lillian Bensley DSHS/DOH Human Research Review Board B.

(6) Human Protections Administrator (e.g., Human Subjects Administrator or Human

Subjects

Contact Person -- cannot be IRB Chairperson):

First Name: **Barbara** Middle Initial: **A.** Last Name: **Silverstein**

Degrees or Suffix (e.g., MD, PhD): MSN, PhD, MPH, CPE Organizational Title: ***SHARP, Research Director***

Human subject protection training last taken on: (09/25/00) (Human Subject Assurance Training 5/25/01)

Telephone: (360) 902-5668 FAX: (360) 902-5672 E-Mail: **silb235@lni.wa.gov**

Address: **P.O. Box 44330**

City: **Olympia** State (if USA): **WA** Zip Code (if USA): **98504-4330**

Country (if outside USA)

(7) Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member):

Acting officially and in an authorized capacity on behalf of this institution, I assure protections for human subjects as specified above. The IRBs above are designated to provide oversight for research under this Assurance. These IRBs will comply with the terms of the Assurance and possess appropriate knowledge of the local context in which this institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I have personally satisfied the education requirements referenced in the Terms of Assurance and will require that all other relevant personnel also do so. I will further require that all such personnel receive appropriate additional initial and continuing education about human subject protection requirements. *(Note: False statements could be cause for invalidating this Assurance and may lead to administrative or legal action.)*

I understand that all collaborating institutions engaged in Federally-supported human subject research must submit their own Assurance.

Signature Gary Moore Date: 6/1/01

First Name: **Gary** Middle Initial: Last Name: **Moore**

Degrees or Suffix (e.g., MD, PhD): Organizational Title: **Director**

Human subject protection training last taken on: (date) **to be added** 6/01/01

Telephone: **(360) 902-4200** FAX: **(306) 902-4202** E-Mail: **Moga235@lni.wa.gov**

Address: **P.O. Box 44001**

City: **Olympia** State (if USA): Zip Code (if USA): **98504-4001**

Country (if outside USA)

NOTE: Facilities operated by the US Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding to OHRP.

(8) HHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to HHS by the above institution is hereby approved for the conduct of Federally-supported research.

Signature of HHS Approving Official: Date: 6/21/2001

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